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530 7590 03/31/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER CRUZ, KATHRIEN ANN	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/646,300  
Filing Date: August 22, 2003  
Appellant(s): FARES ET AL.

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Stephen J. Brown  
Registration No: 43, 519  
Lerner, David, Littenberg, Krumholz & Mentlik, LLP  
600 South Avenue West  
Westfield, New Jersey 07090  
(908) 654-5000  
Attorney  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 11, 2008 appealing from the Office action mailed April 16, 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relie**For the above reasons, it is believed that the rejections should be sustained.

6113888	Castro	9-2000
4552872	Cooper	11-1985
6075056	Quigley	6-2000
6274124	Vollhardt	8-2001

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (US Patent No. 6113888), in view of Cooper et al. (US Patent No. 4552872), in view of Quigley et al. (US Patent No. 6075056), and further in view of Vollhardt et al. (US Patent No. 6274124).

Castro et al. teach, in col. 2 lines 35-55 and claim 21, a mousse composition for topical application that includes 0.001% to about 20% of 1,2-pentanediol and 0.001% to about 20% of 2-methyl-1,3-propanediol, in col. 4 line 60 to col. 5 line 15, Castro et al. teach dermatologically active agents that can be added to the said mousse compositions as including hydrocortisone, dexamethasone, panthenol, phenol, betamethasone, and triamcinolone.

Castro et al. teach, in col. 5 lines 48-55, examples of humectants that can be used in the compositions including glycols such as 2-methyl-1,3-propanediol, 1,2-pentanediol, hexylene glycol, and propylene glycol.

Castro et al. does not teach hydrocortisone acetate and triamcinolone acetate and their respective percentages in the compositions, nor does Castro et al. teach butylene glycol as a solvent or that butylene glycol and propylene glycol can be used together.

Cooper et al. teach, in col. 8 lines 55-63, diol compounds for use in topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols.

Cooper et al. teach, in col. 8 lines 10-50, corticosteroids for use in the topical pharmaceutical compositions including hydrocortisone, hydrocortisone butyrate,

hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. The compositions are to contain a safe and effective amount of corticosteroid from about 0.01% to about 10%, more preferably from about 0.02% to about 5%, and most preferably from about 0.05% to about 5% of corticosteroid. In examples 1-31 Cooper et al. disclose a variety of topical pharmaceutical compositions containing various corticosteroids and diols and that the compositions show enhanced penetration of the corticosteroids when applied topically.

Quigley et al., in col. 7 lines 30-65 and Table A, teach topical formulations that may be in the form of creams, ointments, gels, lotions, foams, powders, shampoos and/or liquid solutions comprising a steroid (0.01-2.5% by weight) and propylene glycol (5-20% by weight), wherein the steroid can be triamcinolone acetate.

Vollhardt teaches, in col. 3 lines 25-45, cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt details that 1,2-pentanediol should preferably represent 0.5% to 6% by weight of the composition, and that 1,2-pentanediol gives improved water resistance to the compositions as compared to 1,2-propanediol and 1,2-hexanediol.

Vollhardt teaches, in col. 3 lines 50-65, that the cosmetic and/or dermatological formulations can be in the form of an emulsion, thin lotion, creamy lotion, light cream, gel, and mousse formulations.

Vollhardt teaches, in col. 4 line 50 to col. 5 line 5, that the cosmetic and/or dermatologically active agents include steroidal anti-inflammatory agents such as hydrocortisone, non-steroidal anti-inflammatory agents, anti-microbial agents and fragrances.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Castro et al. with Cooper et al. in view of Vollhardt.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine Castro et al. with Cooper et al. in view of Quigley et al. and Vollhardt because Castro et al. discloses topical compositions comprising 1,2-pentanediol, an additional glycol (2-methyl-1,3-propanediol), and a dermatologically active agent (which could be hydrocortisone or triamcinolone). Cooper et al. discloses topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols. Cooper et al. discloses that the topical pharmaceutical corticosteroids used in the compositions include hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. Quigley et al. teach topical formulations of triamcinolone acetate and propylene glycol. Vollhardt teaches cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt teaches that the cosmetic or dermatologically active agent can be a steroidal anti-inflammatory such as hydrocortisone. Vollhardt also discloses that 1,2-pentanediol confers greater water

resistance to compositions. It would have been obvious to one of ordinary skill in the art at the time the invention was made that 1,2-pentanediol could be used in the topical pharmaceutical corticosteroid compositions of Cooper et al., in view of Vollhardt, as Castro et al. demonstrated that 1,2-pentanediol could be combined with another diol (propylene glycol or butylenes glycol or both) and that Castro et al., Cooper et al. and Vollhardt's compositions all contain the same dermatologically active agents (steroidal anti-inflammatories). Quigley et al. demonstrate that triamcinolone acetate is an acceptable steroidal anti-inflammatory for glycol formulations. The increased water resistance properties of 1,2-pentanediol containing compositions would motivate one of ordinary skill in the art to combine the compositions. A reasonable chance of success would be expected as the compositions demonstrate that 1,2-pentanediol can be combined with additional diols and all the compositions detailed include steroidal anti-inflammatory agents exemplified by hydrocortisone.

#### **(10) Response to Argument**

In response to appellants arguments against the references individually on pages 5-8 and 16-23 of the brief filed November 21, 2008, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the cited prior art, when taking as a whole, renders the instant invention obvious. Appellants asserts that: "Castro, however, does not disclose any composition containing 1,2-pentanediol

and hydrocortisone, and even the Examiner must admit that it would be serendipitous for one to somehow even select these two classes of components, much less the specific ingredients constituting the presently claimed invention." This is in error. Castro clearly teaches 1,2-pentanediol which is a species of the genus of pentylene glycols (see claims 20 and 21). Castro clearly teaches adding "dermatologically active agents" to the composition (claim 16). In looking to the specification to see what is meant by "dermatologically active agents", it is found in column 4, line 65 that hydrocortisone is contemplated by Castro. Therefore, it is not an unreasonable stretch for one of ordinary skill in the art of cosmetics and dermatological compositions to understand that Castro fairly teaches a composition with hydrocortisone and a pentylene glycol. Any beneficial effects of this combination of ingredients would have been present in the composition of Castro.

Appellant assert that the Examiner has failed to address the Fares Declaration and the evidence of unexpected results in the specification. The present Examiner of record has considered the Fares Declaration filed 4/1/05 which addresses the secondary references of Cooper and Vollhardt and does not address the primary reference of Castro who teaches a pentylene glycol. Thus that Declaration is not persuasive because Castro clearly teaches a pentylene glycol. The unexpected results presented in the specification at [0034], for example, demonstrating greater release of hydrocortisone from the gel of the present invention over the commercial products would have also been present in the composition of Castro and would not have been surprising or unexpected. "A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The fact that hydrocortisone is more soluble in pentylene glycol than other glycols would have been observed by Castro. The present Examiner has not ignored the evidence of record, has considered the Declaration by Fares, and has considered the data in the specification as filed.

Respectfully, it is the position of the Examiner the claims are not commensurate in scope with the showing and the rejection is maintained. From MPEP 716.02, also 716.02 (a) - (g): It is applicant's burden to demonstrate unexpected results over the closest prior art. Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). Appellants argues on pages 16- 19, 22-23 of the appeal brief filed November 21, 2008, that the combination of references (e.g. Cooper, Castro and Quigley) would render one or more of the products unsatisfactory for their intended purposes. However, Appellant does not state why they render this conclusion and therefore this argument is not persuasive because the references teach to use the products in the composition claimed in a similar manner, regardless of how many different products that the references list to form the desired composition. Further,

appellants are claiming a composition not intended use, therefore the argument that render one of the references unsatisfactory from it's intended is irrelevant.

Appellants allege that there is no motivation to combine Cooper and Vollhardt. The Examiner disagrees because Cooper et al. teach, in col. 8 lines 10-50, corticosteroids for use in the topical pharmaceutical compositions including hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. The compositions are to contain a safe and effective amount of corticosteroid from about 0.01% to about 10%, more preferably from about 0.02% to about 5%, and most preferably from about 0.05% to about 5% of corticosteroid. In examples 1-31 Cooper et al. disclose a variety of topical pharmaceutical compositions containing various corticosteroids and diols and that the compositions show enhanced penetration of the corticosteroids when applied topically. And Vollhardt Vollhardt teaches, in col. 3 lines 25-45, cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt details that 1,2-pentanediol should preferably represent 0.5% to 6% by weight of the composition, and that 1,2-pentanediol gives improved water resistance to the compositions as compared to 1,2-propanediol and 1,2- hexanediol. Vollhardt teaches, in col. 3 lines 50-65, that the cosmetic and/or dermatological formulations can be in the form of an emulsion, thin lotion, creamy lotion, light cream, gel, and mousse formulations. Vollhardt teaches, in col. 4 line 50 to col. 5 line 5, that the cosmetic and/or dermatologically active agents include steroidal anti-inflammatory

agents such as hydrocortisone, non-steroidal anti-inflammatory agents, anti-microbial agents and fragrances. Vollhardt teaches, in col. 3 lines 25-45, cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt details that 1,2-pentanediol should preferably represent 0.5% to 6% by weight of the composition, and that 1,2-pentanediol gives improved water resistance to the compositions as compared to 1,2-propanediol and 1,2-hexanediol. Vollhardt teaches, in col. 3 lines 50-65, that the cosmetic and/or dermatological formulations can be in the form of an emulsion, thin lotion, creamy lotion, light cream, gel, and mousse formulations. Vollhardt teaches, in col. 4 line 50 to col. 5 line 5, that the cosmetic and/or dermatologically active agents include steroidal anti-inflammatory agents such as hydrocortisone, non-steroidal anti-inflammatory agents, anti-microbial agents and fragrances. It would have been obvious to combine Cooper and Vollhardt because Vollhardt compositions contain the same active agents (e.g. steroidal, anti-inflammatories) and the use of pentyleneglycols. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Castro et al. with Cooper et al. in view of Vollhardt. Again, appellant are reminded that arguments against the references individually on pages 5-8 and 16-23 of the brief filed November 21, 2008, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Appellant allege that Quigley discloses that the penetration of the steroid through the skin can lead to undesirable and potentially dangerous side effects on page 22-23

on the appeal brief dated November 21, 2008. However, Quigley was referring to the combination of steroids and antifungal agents (column 1, lines 27-32). Because steroids can penetrate the skin and can cause undesirable side effects from the fungicide. Thus, this argument is not persuasive.

In conclusion, since the primary reference of Castro teaches and suggests a composition with hydrocortisone and pentylene glycol then any beneficial solubility properties would have been observed by Castro. In addition, the claims are not commensurate in scope with the data in the specification as filed which is the hydrocortisone gel in Example 6 on page 16 which includes 3 different glycols, a carbomer, and a polyacrylate which would all have an influence on the solubility of the hydrocortisone. Accordingly, the present Examiner maintains the rejections for the reasons of record and those stated above.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Art Unit: 1617

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/San-ming Hui/

Primary Examiner, Art Unit 1617

Conferees:

/KATHRIEN CRUZ/

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617